

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

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BIOVAIL LABORATORIES )	
INTERNATIONAL SRL, )	
) )	
Plaintiff, ) )	C.A. Nos. 05-586 (GMS)
v. ) )	05-730 (GMS)
) )	06-620 (GMS)
) )	
ANDRX PHARMACEUTICALS, LLC and ) )	CONSOLIDATED
ANDRX CORPORATION, ) )	
) )	
Defendants. ) )	
) )	

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**ORDER**

1. The plaintiff, Biovail Laboratories SRL (“Biovail”), filed the above-captioned actions against Andrx Pharmaceuticals LLC and Andrx Corporation (“Andrx”), alleging infringement of United States Patent Nos. 5,529,791 (the “‘791 patent”) and 7,108,866 (the “‘866 patent”), which are directed to extended release tablets of varying dosages containing the active ingredient diltiazem hydrochloride, which are marketed in the United States under the trade name Cardizem® LA, and are indicated for the treatment of hypertension and the management of chronic stable angina.<sup>1</sup>
2. On January 3, 2007, the case was reassigned to this court.

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<sup>1</sup> On August 10, 2005, Biovail filed the 05-586 action against Andrx, alleging infringement of the ‘791 patent by dosages of Andrx’s generic diltiazem hydrochloride product. On October 14, 2005, Biovail filed the 05-730 action against Andrx, alleging infringement of the ‘791 patent by additional dosages of Andrx’s product. On October 4, 2006, Biovail filed the 06-620 action against Andrx for infringement of the’866 patent. On February 22, 2006 and October 17, 2006, the Honorable Kent A. Jordan (“Judge Jordan”) issued Orders consolidating the 05-586 action with the 05-730 and 06-620 actions. Pursuant to Judge Jordan’s Orders, 05-586 action has been designated as the Lead Case for the purpose of filing of documents with the court.

3. On January 30, 2007, the court reset the trial of this matter from its last scheduled date of January 14, 2008 to October 9, 2007.

4. On March 20 2007, Andrx filed a Motion for Leave to File a First Amended Answer and Counterclaims (D.I. 139). Andrx's motion seeks to add the defense of patent unenforceability due to inequitable conduct, as well as a counterclaims for declaratory judgment of unenforceability.

5. On April 11, 2007, Biovail filed an answering brief (D.I. 155) opposing Andrx's motion. Biovail contends that the court should deny the motion for two reasons: (1) Andrx's allegation of inequitable conduct is baseless and futile; and (2) Andrx has acted with undue delay in bringing its motion which, given the time remaining before trial, will unduly prejudice Biovail.

6. The gravamen of the dispute between the parties is Andrx's assertion that the delay in filing for leave to amend resulted from inappropriate resistance by Biovail to Andrx's taking certain depositions, and Biovail's counter that these depositions in no way informed Andrx's judgment on this issue. Biovail argues that this is so, because all the factual bases for the allegations of inequitable conduct were revealed by documents, which were produced and otherwise known to Andrx early this litigation. Andrx asserts that those depositions were, indeed, critical and did not take place until the court issued an order forcing Biovail to produce the witnesses in question. Andrx contends that the taking of these depositions was crucial to its decision of whether to seek to amend its answer because, in order to comply with the pleading requirements of Rule 9(b) of the Federal Rules of Civil Procedure, Andrx needed to learn and confirm the bases of its allegations of inequitable conduct.

7. Leave to amend an answer should be "freely given when justice so requires." Fed. R. Civ.

P. 15(a). The court has discretion to deny leave to amend when there exists undue delay, bad faith, dilatory motive or undue prejudice to the opposing party, or when the amendment would be futile.

*See Foman v. Davis*, 371 U.S. 178, 182 (1962); *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997).

8. After having considered Andrx's proposed amendment, the parties' submissions on the issue, and the pertinent law, the court concludes that leave to amend should be granted. Given the circumstances, including those attendant to the delayed depositions discussed above, and the court's ability to ameliorate any adverse impact upon Biovail of the belated insertion of the defense of inequitable conduct into this action by, among other remedies, adjusting the schedule, the court believes this to be a fair result.

9. In addition, the court is persuaded that, under the circumstances of this case, a contrary ruling would tend to encourage knee jerk, thoughtless, and poorly grounded assertions of inequitable conduct by defendants in patent infringement actions. The court is mindful of the need to be vigilant to attempts by parties to achieve an unfair advantage by delaying the making of such assertions, however, it does not believe that concern obtains here.

10. The court also concludes that Andrx's amendment is not futile, because it includes factual contentions which, if proved, could provide the basis for a finding of unenforceability.

Therefore, IT IS HEREBY ORDERED that:

1. Andrx's Motion for Leave to File a First Amended Answer and Counterclaims (D.I. 139) is GRANTED.
2. Andrx's amended answer and counterclaim, which is attached to its motion to amend, is deemed filed.

3. The court will hold a teleconference to discuss with the parties what, if any, adjustments to the schedule might be needed to accommodate the interest of all parties, including the court.

Dated: May 4, 2007

/s/ Gregory M. Sleet  
UNITED STATES DISTRICT JUDGE